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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BOECKMANN, JASON J	

ART UNIT	PAPER NUMBER
3752	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,307	ROBIDA, TODD	
	Examiner	Art Unit	
	Jason J. Boeckmann	3752	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/16/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *2, 4, 11, 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/16/2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/10/05 3/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings were received on 3/16/2006. These drawings are not accepted, see rejections below and on the attached PTO-948 form.

Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Examiner notes that in paragraph 12 of the specification, figure 1 is indicated as prior art. In addition, the first sentences of paragraphs 24 and 27 discuss figure 1 as being well known in the art.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first position, second position and the default neutral position of the valve must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In response to the applicant's argument, the examiner is objecting to the drawings under rule 37 CFR 1.83(a), not 37 CFR 1.81, which clearly states that every feature of the invention specified in the claims must be shown in the drawings. The neutral position of the valve is not shown in figure 11 nor does the specification indicate that figure 11 represents the neutral position of the valve. Furthermore, the expanded and annotated figure on page 2 of the remarks is not part of the applicant's disclosure and therefore is not considered. Regarding the new drawings 17a and 17b, a schematic

drawing cannot represent the open and closed positions of the valve when only details of relative positions of the internal parts and features of the valve can clearly show the respective positions.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

- In figure 9, reference numbers 80a and 80b do not appear in the specification
- In figure 11, reference numbers 72, 83 and 81 do not appear in the specification.
- In figures 12 and 13, the reference number 120 does not appear in the specification.
- In figures 14-16, reference number 140 does on appear in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because in the new figures 17a and 17b, the pipette needle appears to be numbered incorrectly. In the specification it is referred to as number 11, but examiner believes that it is labeled 17 in the figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 11 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Examiner is unsure of how the valve returns to its neutral state without the use of a spring return mechanism. There is no disclosure of any internal parts or features to the valve that indicate how it would return to a default neutral state when the supply pressure operating the valve is removed, nor does the specification explain how the valve returns to its neutral state.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 recites the limitation "all valve seats" in line 7. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "all valve seats" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "all valve seats" in line 14. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 5-7, 10, 12-18 20 and 2, 4, 11, 19, as well as understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (figures 1-8) in view of Kintner (3,426,799).

The applicants admitted prior art discloses a medical device coating unit comprising a three-way valve (70), a solution reservoir (11) connected to a first port, a solution receptacle (14) connected to a second port, and a solution outlet (12) connected to a third port. The medical device being adapted to withdraw the coating solution form the reservoir (11) through the valve (70) and into the solution receptacle (14) and expel the coating material from the solution receptacle (14) through the valve (70) and through the solution outlet (12). The admitted prior art does not specifically disclose that the valve is a pneumatic actuated three-way valve. However, Kintner

shows a pneumatic actuated three-way valve (figure 3) with no spring return mechanism, comprising first (22), second (23) and third (24) valve ports and two pneumatic ports (8 and 6). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to substitute the new pneumatic actuated three-way valve of Kintner for the three-way valve of figure 1 in order to make the medical device automated and more reliable.

Regarding claims 2 and 11, as well as understood, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 3, 4, as well as understood, 12 and 13, the solution receptacle comprises a syringe (14) and the solution outlet comprises a spray nozzle (12).

Regarding claims 6 and 20, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a pressure source, to the medical device of the admitted prior art as modified by Kintner, that provides a pressure within a range of about 300 kilo-Pascals to about 500 kilo-Pascals in order to move the valve form the first position to the second position more accurately.

Regarding claim 7, the medical device of the admitted prior art as modified by Kintner includes a first tube (13a) having a first diameter coupled to the first port (8) and a second tube (13c) having a second diameter coupled to the second port (6).

Regarding claim 10, the medical device of the admitted prior art as modified by Kintner includes one or more disposable fittings (16a, 16b, 16c, 16d).

With respect to claims 14-18 and 19, as well as understood, the apparatus shown by the applicants admitted prior art as modified by Kintner is capable of performing the method or steps in the claims.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the applicant's admitted prior art (figures 1-8) in view of Kintner (3,426,799) further in view of Chemline Plastics Ltd. (2001).

The applicant's admitted prior art as modified by Kintner shows all aspects of the applicant's invention as in claim 5, including threaded inserts (14, 15, 16), but does not specifically disclose that it contains stainless steel threaded inserts. However, Chemline Plastics Ltd. shows a pneumatic valve with stainless steel threaded inserts (page 2). It would have been obvious to on of ordinary skill in the art at the time of the applicant's invention to substitute the stainless steel threaded inserts of Chemline Ltd. for the threaded inserts of the applicant's admitted prior, art as modified by Brown, in order to prevent corrosion. Additionally, it is well known that stainless steel is an obvious choice of material for medical devices due to its ability to resist corrosion and be easily cleaned. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to make the valve body out of stainless steel in order to prevent corrosion.

Claims 1, 5-7, 14-18, 20 and 2, 11, 19, as well as understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Liston (3,817,425) in view of Kintner (3,426,799).

Liston discloses a medical device coating unit comprising a three-way valve (300), a solution reservoir (272) connected to a first port (305), a solution receptacle (291) connected to a second port (307), and a solution outlet (226) connected to a third port (306). The medical device being adapted to withdraw the coating solution form the reservoir (272) through the valve (300) and into the solution receptacle (291) and expel the coating material from the solution receptacle (291) through the valve (300) and through the solution outlet (226). Liston does not specifically disclose that the valve is a pneumatic actuated three-way valve. However, Kintner shows a pneumatic actuated three-way valve (figure 3) with no spring return mechanism, comprising first (22), second (23) and third (24) valve ports and two pneumatic ports (8 and 6). It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to substitute the new pneumatic actuated three-way valve of Kintner for the three-way valve of Liston in order to make the medical device automated and more reliable

Regarding claims 2 and 11, as well as understood, the three-way valve of Kintner comprises a position in which all valve seats remain open (see figure 3).

Regarding claims 6 and 20, one of ordinary skill in the art at the time of the applicant's invention would be able to supply a pressure source, to the medical device of Liston as modified by Kintner, that provides a pressure within a range of about 300

kilo-Pascals to about 500 kilo-Pascals in order to move the valve form the first position to the second position more accurately.

Regarding claim 7, the medical device of Liston as modified by Kintner includes a first tube (275) having a first diameter coupled to the first port (305) and a second tube (298) having a second diameter coupled to the second port (307).

With respect to claims 14-18 and 19, as well as understood, the apparatus shown by Liston as modified by Kintner is capable of performing the method or steps in the claims.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason J. Boeckmann whose telephone number is (571) 272-2708. The examiner can normally be reached on 7:30 - 5:00 m-f, first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David A. Scherbel can be reached on (571) 272-4919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JJB JJB 5/24/06

David A. Scherbel
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